NOV 0 2 2001

K013326

Attachment D

SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
DATASCOPE'S 8Fr. Polyimide Alt B 25, 34 & 40cc Intra-Aortic Balloon Catheters

Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter:	Datascope Corp. Cardiac Assist Division
Address	15 Law Drive Fairfield, NJ 07004
Contact Person:	JoAnn Wolf Regulatory Affairs Associate

B. DEVICE INFORMATION

Generic Name:	Intra-Aortic Balloon Catheter (IAB)
Trade Name:	Datascope's Intra-Aortic Balloon Catheter (IAB)
Classification Name:	Intra-Aortic Balloon Catheters (IAB) are classified under 21 CFR 870.3535

C. PREDICATE DEVICE INFORMATION

Datascope's 8Fr. Polyimide Alt B 25, 34 & 40cc Intra-Aortic Balloon Catheters (IAB) are substantially equivalent to the following marketed devices:

- K003598, Datascope Profile 8 Fr. Alt B Intra-Aortic Balloon Catheters w/Gas Lumen Insert (S/E 12/21/00).
- K994157, Datascope 8Fr. Polyimide Intra-Aortic Balloon Catheters (S/E 3/13/00)
- K943896, Datascope Staged Guide Wire (S/E 12/22/95)

D. DEVICE DESCRIPTION/INTENDED USE

The intra-aortic balloon is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular functioning during the following situations:

- Refractory ventricular failure
- Cardiogenic shock
- Unstable refractory angina
- Impending infarction
- Mechanical complications due to acute myocardial infarction
- Ischemic related intractable ventricular arrhythmias
- Cardiac support for high risk surgical patients and coronary angiography or angioplasty patients
- Septic shock
- Weaning from cardiopulmonary bypass
- Interoperative pulsatile flow generation
- Support for failed angioplasty and valvuloplasty

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's 8Fr. Polyimide Alt B 25, 34 & 40cc Catheters are substantially equivalent to the predicate devices with regard to intended use. Material modifications to Datascope's 8Fr. catheters include adding a previously cleared alternate membrane material (Alt B), adding a full length polyimide co-lumen with blue colorant to the previously cleared polyimide co-lumen, and changing the catheter tip to a composite of previously cleared catheter tip materials. A dimensional change to the catheter's inner lumen includes an inner diameter change from .023" to .030". In addition, a modified .025 stainless steel guide wire has replaced the nitinol guide wire the insertion kit. These modifications to the 8Fr. Polyimide Alt B IAB have been demonstrated not to affect safety or efficacy of the device.

F. NON-CLINICAL TESTS

The results of in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed devices.

G. CLINICAL TESTS

There have been no clinical evaluations of the new device.

H. CONCLUSIONS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Ms. JoAnn Wolf
Regulatory Affairs Associate
Datascope Corporation
Cardiac Assist Division
15 Law Drive
Fairfield, NJ 07004

Re: K013326
Datascope 8 Fr. Polyimide Alt B Intra-Aortic Balloon Catheter
Regulation Number: 870.3535
Regulation Name: Intra-Aortic balloon and control system
Regulatory Class: Class III
Product Code: 74 DSP
Dated: October 4, 2001
Received: October 5, 2001

Dear Ms. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013326

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Attachment B

Indications for Use Statement

510(k) Number K013326

Device Name Datascope 8Fr. Polyimide Alt B 25, 34 & 40cc Intra-Aortic Balloon Catheter

Indications for Use The Datascope 8Fr. Polyimide Alt B Intra-Aortic Balloon Catheter has the following indications for use:

1. Refractory ventricular failure.
2. Cardiogenic shock.
3. Unstable refractory angina.
4. Impending infarction.
5. Mechanical complications due to acute myocardial infarction, i.e., ventricular septal defect, mitral regurgitation or papillary muscle rupture.
6. Ischemia related intractable ventricular arrhythmias.
7. Cardiac support for high risk general surgical patients and coronary angiography/angioplasty patients.
8. Septic shock.
9. Weaning from cardiopulmonary bypass.
10. Intraoperative pulsatile flow generation.
11. Support for failed angioplasty and valvuloplasty.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CCRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013326

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)